

**METHOD AND APPARATUS FOR COMPUTER CONTROLLED RARE CELL,
INCLUDING FETAL CELL, BASED DIAGNOSIS**

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This application is a continuation of United States Patent Application No. 09/724,384 filed November 28, 2000, ^{now abandoned} which is a divisional of United States Application No. 09/421,956 filed October 20, 1999, ^{now abandoned} which is a continuation of PCT/US99/10026 filed May 7, 1999, which claims priority of United States Provisional Patent Application No. 60/84,893, filed May 9, 1998, which is incorporated by reference herein in its entirety.

1. FIELD OF THE INVENTION

The present invention relates to computer controlled methods and apparatus for obtaining and preparing cell samples and for identifying a rare cell of interest from a field of
15 cells and making a diagnosis based on a characteristic of a rare cell selected in the field. In one important embodiment, the invention relates to obtaining and preparing a maternal blood sample for fetal cell based prenatal diagnosis.

2. BACKGROUND OF THE INVENTION

20 The advent of DNA based prenatal diagnosis for human genetic disorders has led to the development of a number of new diagnostic methods. These diagnostic methods permit early detection and consequently informed decisions and intervention with respect to fetus having a genetic disorder. These methods, however, have a number of disadvantages. Each of the new diagnostic methods with which this discussion is concerned requires that a
25 sample of isolated fetal cells be obtained, so that the DNA of the fetus may be examined or tested for signs of specific genetic disorders. The disadvantages of these modern methods stem primarily from the need to obtain a sample of fetal cells. Currently, fetal cells are obtained by invasive procedures requiring obstetric intervention by amniocentesis or by chorionic villus sampling. These highly specialized procedures carry a small, but
30 significant, risk to the fetus. Early in pregnancy, the level of risk to the fetus is high and the number of cells obtained is low. Therefore, results of these procedures often are not obtained until 18-20 weeks of pregnancy.

One modern procedure for obtaining fetal cells relies on leakage of fetal cells into the maternal circulation. By simply drawing a sample of maternal blood, it is theoretically
35 possible to obtain fetal cell material in a sufficient quantity for prenatal diagnosis by DNA

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